



UNITED STATES PATENT AND TRADEMARK OFFICE

[Signature]
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,071	05/04/2006	Antonio Camargo	4705-0111PUS1	8916
2292 7590 09/13/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER LI, QIAN JANICE	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 09/13/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.		Applicant(s)	
	10/538,071		CAMARGO ET AL.	
	Examiner		Art Unit	
	Q. Janice Li, M.D.		1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 117-139 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 117-139 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed 7/9/07 are acknowledged. Claims 1-116 have been canceled. Claims 117-139 are newly submitted. The new claims necessitated amendment of previous restriction according to 35 U.S. C. 121 & 372.

Election/Restrictions

1. This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1. Restriction is required under 35 U.S.C. 121 and 372.

Group I, Claims 117, 118, 126, drawn to a method of diagnosis by assessing the level of EOPA protein expression using an immunoassay;

Group II, claims 117, 119, 120, drawn to a method of diagnosis by assessing the enzymatic activity of EOPA via hydrolysis;

Group III, claims 117, 119, 121, 122, drawn to a method of diagnosis by assessing the enzymatic activity of EOPA via a fluorogenic peptide substrate;

Group IV, claims 117, 123-125, drawn to a method of diagnosis by assessing the binding of Lis1 or Disc1 to EOPA;

Group V, Claim 117, drawn to a method of diagnosis by assessing the level of EOPA mRNA expression using an immunoassay;

Group VI, claims 127, 128, drawn to a method for identifying a compound comprising measuring the activity of EOPA by hydrolysis in the presence or absence of the compound;

Group VII, claims 127, 129, 130, drawn to a method for identifying a compound comprising measuring the activity of EOPA by a fluorogenic peptide substrate in the presence or absence of the compound;

Group VIII, claims 131, 132, drawn to a method for identifying a compound comprising measuring the binding of Lis 1 or Disc 1 to EOPA in the presence or absence of the compound;

Group IX, claims 133-136, 139, drawn to a peptide having activity of an inhibitor of EOPA and a method of using such for inhibiting EOPA activity;

Group X, claims 137, 138, drawn to an antibody that specifically binds to EOPA.

Claim 117 link(s) inventions II-V, and I. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 117.

Claim 127 link(s) inventions VI and VII. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 127. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the

amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116;

amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. The invention listed as groups I-X do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions II-X and I are directed to related inventions. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, I-VIII are directed to different methods of diagnosis and screening. The different methods have different method steps and mode of operation, use different criteria for assessment, and would require different search field, and technical considerations. Groups IX and X are directed to structural distinct compounds that belong to different chemical categories. 37

Art Unit: 1633

CFR 1.475 does not provide for more than one product/method. Since multiple processes of using/producing are claimed, unity of invention is lacking and restriction is required.

Further, as shown in the applicant's IDS, Camargo et al (1985) disclose an antibody that specifically recognizes EOPA protein, but not a peptide that inhibit EOPA activity. The expression "special technical features" shall mean those technical features that define a contribution, which **each** of the claimed inventions, considered **as a whole**, makes over the prior art. Consequently, the special technical feature of group X does not provide a contribution over the prior art as a whole with groups IX, so unity of invention is lacking.

The differences in the special technical features of the Inventions I-X are further underscored by their divergent classification and independent search criteria.

Because these inventions are lack unity for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Each of invention groups I-VIII further embraces multiple species, each drawn to a method of diagnosis for a specific disease, or screening for a drug capable of treating a specific disease, including a congenital disease of brain, a brain degenerative disease, or schizophrenia. These diseases have different etiology, pathology, and require different search criteria and technical consideration. Upon election of one of the groups I-VIII for examination, it is necessary to further elect a species drawn to a specific disease such as schizophrenia.

Each of invention groups II and VI further embraces multiple species drawn to hydrolysis of different chemical bonds. Upon election of one of the groups II or VI for examination, it is necessary to further elect a species drawn to a specific chemical bond such as bradykinin.

Invention group IX further embraces multiple species drawn to structural distinct peptide. Upon election of groups IX for examination, it is necessary to further elect a species drawn to a specific peptide such as SEQ ID No: 5 or bradykinin.

Applicant is required under 35 U.S.C. 121 & 372 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic, i.e. no single claim is drawn to a particular species of an invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is

Art Unit: 1633

allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143), and a listing of all claims readable thereon, including any claims subsequently added.

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on 571-272-0739. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

**Q. JANICE LI, M.D.
PRIMARY EXAMINER**



Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

Application/Control Number: 10/538,071
Art Unit: 1633

Page 10

QJL
September 6, 2007